



N.C. Department of Health
and Human Services



CERTIFICATE OF NEED OVERVIEW of DIAGNOSTIC CENTERS

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MARCH 18, 2014

What is a Diagnostic Center?*



- Freestanding facility, program or provider, including, but not limited to:
 - ✦ Physician office
 - ✦ Clinical lab
 - ✦ Radiology center
 - ✦ Mobile diagnostic program

*As defined by the NC Certificate of Need (CON) Statute

Definition Continued



- Total cost of all the medical diagnostic equipment utilized by the facility which cost \$10,000 or more exceeds \$500,000. Cost includes:
 - Cost of the equipment (fair market value or cost, whichever is greater)
 - Studies, surveys, designs, plans, working drawings, specifications
 - Construction
 - Installation
 - Other Activities essential to acquiring & making equipment operational

How are Diagnostic Centers Regulated?



- DHSR does not license or certify diagnostic centers, except:
 - DHSR Acute & Home Care Licensure & Certification Section does certify and provide oversight for:
 - ✦ Clinical labs – Clinical Laboratory Improvement Amendments (CLIA)
 - ✦ Portable x-ray supplier service
 - A clinical lab and portable x-ray service can be designated as diagnostic centers if they meet the criteria.

How Regulated Continued



- For health and safety, DHSR Radiation Protection Section requires:
 - Registration of ionizing radiation diagnostic equipment
 - ✦ CT
 - ✦ X-ray
 - ✦ Mammography
 - Training, shielding & installation oversight
- DHSR CON Section regulates diagnostic centers by requiring a facility to apply for a CON to become a diagnostic center when the total cost of all medical diagnostic equipment costing \$10,000 or more totals \$500,000.

Diagnostic Centers Reviewed Since March 1993*



- 310 diagnostic center applications reviewed
 - 63% Magnetic Resonance Imaging (MRI) Scanner
 - 3% Positron Emission Tomography (PET) Scanner
 - 34% Other equipment
 - Computed Tomography (CT) Scanner
 - Mammography
 - Bone density
 - Ultrasound
 - X-ray

Diagnostic Centers Reviewed Continued



- 165 diagnostic center CON approvals
 - 51% MRI
 - 2% PET
 - 47% Other equipment
- 146 not approved
 - Part of competitive review, or
 - Withdrawn after approval